510(k) Summary

as required by 807.92

K013054

1. Company Identification

MAR 4 2002

Konica Corporation
591-7,Kamihirose,Sayama-shi,Saitama-ken 350-1321 Japan
Tel : 011-81-42-954-4529
Fax : 011-81-42-954-6677

2. Official Correspondent

Koji Kubo (Mr.)
Safety Standard Team
Standards & Regulations Section
Planning Department
Imaging Systems Division

3. Date of Submission

August 20, 2001

4. Device Trade name

Konica Direct Digitizer REGIUS MODEL 350

5. Common Name

Film Digitizer (CR IMAGER)

6. Classification

Medical image digitizer was reviewed by the Radiology Panel and are classified in Class II per 21 CFR 892. 2030.

7. Predicate Device

Konica Direct Digitizer, Model 330, 510(k) number: K980873

8. Description of Device

The Konica Direct Digitizer, REGIUS MODEL 350 is an X-ray image controller which uses a stimulative phosphor as X-ray detector and controls and manages digital X-ray image file processing.

The system consists of an operator console, an image buffer section (hard disk) and control section. The operator console consists of an operation CRT display that has a touch panel function, and a keyboard for entering text. An image file received from an industry-standard X-ray film cassette is processed using automatic tonal processing and is then transferred to an externally connected device including a host computer or CR printer.

For more information, please refer to the attachment.

9. Intended Use

The Konica Direct Digitizer, REGIUS MODEL 350 is an X-ray image controller which uses a Stimulative phosphor as X-ray detector and intended to control and manage digital X-ray image file processing.

10. Substantial Equivalence to Predicate Device

The Konica Direct Digitizer, REGIUS MODEL 350 is substantially equivalent to our Konica Direct Digitizer REGIUS MODEL330,510(k) number: K980873.
Comparison of the principal characteristics of the two devices which are pertinent to Specification performance is shown below.

Item	Approved Medical Device	Medical Device Applied for Approval	Remarks
Applicant, etc.	Company : Konica Corporation Product Name : Konica Direct Digitizer REGIUS MODEL 330 Approval No. : K980873	Company : Konica Corporation Product Name : Konica Direct Digitizer REGIUS MODEL 350	
Configuration	The device consists of a reading unit(the unit is combined with an elevator platform which horizontally positions the reading device to suit to the height of the patient through up-and-down movement) and a control unit which performs the image display, image transfer, etc.	The device consists of a reading unit(the unit is combined with an elevator platform which horizontally positions the reading device to suit to the height of the patient through up-and-down movement) and a control unit which performs the image display, image transfer, etc.	Same as the registered model
Principle of Operation	X-ray image data of a patient is temporarily stored in the stimulable phosphor plate that is contained in the device. <Exposure> After that the surface of the plate is scanned in time sequence by laser beam so that the amount of light according to the amount of X-ray stored in the plate is emitted. The emitted light will be collected and converted to electric signal by a photomultiplier tube (PMT), then to digital signal by an A/D converter, etc.. <Reading> After reading is completed, light of halogen lamp is applied to the surface of the plate in order to erase the after-image. <Erase> Through this chain of operations (Exposure → Reading→Erase), repeat-use of the plate is made possible. The image data after being converted to digital signal is then transferred to the controller and displayed on CRT. After checking the image, the image data will be transferred to the printer, magneto-optic disk drive, or host computer.	X-ray image data of a patient is temporarily stored in the stimulable phosphor plate that is contained in the device. <Exposure> After that the surface of the plate is scanned in time sequence by laser beam so that the amount of light according to the amount of X-ray stored in the plate is emitted. The emitted light will be collected and converted to electric signal by a photomultiplier tube (PMT), then to digital signal by an A/D converter, etc.. <Reading> After reading is completed, light of halogen lamp is applied to the surface of the plate in order to erase the after-image. <Erase> Through this chain of operations (Exposure → Reading→Erase), repeat-use of the plate is made possible. The image data after being converted to digital signal is then transferred to the controller and displayed on CRT. After checking the image, the image data will be transferred to the printer, magneto-optic disk drive, or host computer.	Same as the registered model

Specifications	● Type : Exclusively for the exposure of stand position. ● Cycle Time : Max. 25 sec. or less. (14x17in at 175 μ m reading pitch) ● Exposure Size : 5 sizes (14x17in, 14x14in, 11x14in, 10x12in, 8x10in) ● Maximum Pixels(Read) : Max. 4096 x 4924 pixel ● Sampling Pitch : 9 types (87.5, 100, 125, 137.5, 150, 175, 200, 212.5, 350 μ m) ● Gray Levels : 4096 ● Laser Source: Laser Diode 780nm ● Laser Power: 200mW ● Laser Modulator; none ● Elevation stroke : 575mm or more ● Power Source ; AC200V, 50/60Hz ● Power Consumption; 1.8kW ● Operational Environment : Temperature : 20～30℃ Humidity : 35～80%RH (Applicable to reading unit only)	● Type : Exclusively for the exposure of stand position ● Cycle Time : Max. 17 sec. or less. (17x17in at 175 μ m reading pitch) ● Exposure Size : 6 sizes (17x17in,14x17in, 14x14in, , 11x14in 10x12in, 8x10in) ● Maximum Pixels(Read) : Max. 4860 x 4860 pixel ● Sampling Pitch : 2 types (87.5, 175 μ m) ● Gray Levels : 4096 ● Laser Source: Laser Diode 690nm ● Laser Power: 60mW ● Laser Modulator; none ● Elevation stroke : 790mm or more ● Power Source ; AC100/200V, 50/60Hz ● Power Consumption; 1.3kW ● Operational Environment : Temperature : 15～30℃ Humidity : 40～80%RH	Upgrated.
Purpose of Use	The device is intended for the use at the X-ray department of the hospital, etc. in order to convert X-ray image data to digital signal and to transfer the converted data to printer, magneto-optic disk driver, image display device, etc.	The device is intended for the use at the X-ray department of the hospital, etc. in order to convert X-ray image data to digital signal and to transfer the converted data to printer, filing system, image display device, etc.	Same as the approved device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 4 2002

Konica Corporation
% Mr. Shinichi Yamanaka
Cosmos Corporation
319 Akeno, Obata-cho
Watarai-gun, Mieken
519-05 JAPAN

Re: K013054
Trade/Device Name: Konica Direct Digitizer Regius Model 350
Regulation Number: 21 CFR 892.1630
Regulation Name: Electrostatic x-ray imaging system
Regulatory Class: II
Product Code: 90 MGB
Dated: November 26, 2001
Received: November 3, 2001

Dear Mr. Yamanaka:

This letter corrects our substantially equivalent letter of March 4, 2002 regarding the date on which it was issued. The effective date of this letter is March 1, 2002.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent [(for the indications for use stated in the enclosure)] to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-__. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

510(k) Number (If known): Not known K013054

Device Name: KONICA DIRECT DIGITIZER, REGIUS MODEL 350

Indications for Use:

The Konica Direct Digitizer, REGIUS MODEL 350 is an X-ray image controller which uses a stimulative phosphor as X-ray detector and controls and manages digital X-ray image file processing.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Prescription Use √ OR Over-The-Counter Use

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013054